

REGISTRATION REPORT

Part A

Risk Management

Product code: DSPF016

Product name: PYGMALION

Chemical active substance:

Potassium Phosphonates, 755 g/L

Southern Zone and Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: DE SANGOSSE

Date: 23/10/2025

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	6
2.5	Risk management	6
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorisation decision and risk management	17
3.1	Physical and chemical properties (Part B, Section 2)	17
3.2	Efficacy (Part B, Section 3)	17
3.3	Methods of analysis (Part B, Section 5)	17
3.3.1	Analytical method for the formulation	17
3.3.2	Analytical methods for residues	17
3.4	Mammalian toxicology (Part B, Section 6)	18
3.4.1	Acute toxicity	18
3.4.2	Operator exposure	18
3.4.3	Worker exposure	20
3.4.4	Bystander exposure	22
3.4.5	Resident exposure	22
3.5	Residues and consumer exposure (Part B, Section 7)	24
3.6	Environmental fate and behaviour (Part B, Section 8)	26
3.7	Ecotoxicology (Part B, Section 9)	26
3.8	Relevance of metabolites (Part B, Section 10)	27
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	27
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation	27

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

5.1.1	Post-authorisation monitoring.....	27
5.1.2	Post-authorisation data requirements	27
Appendix 1	Copy of the product authorisation	28
Appendix 2	Copy of the product label	29

PART A

RISK MANAGEMENT

1 Details of the application

The company DE SANGOSSE has requested a marketing authorisation in France for the product PYGMALION (product code: DSPF016), containing 755 g/L potassium phosphonates¹ as a fungicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of DE SANGOSSE's application submitted on 30/06/2023 to market PYGMALION (DSPF016) in France (product uses described under point 2.3). France acted as a zonal (zRMS) and interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the label extension of this product in France and in other Member States (MSs) of the European Union.

The present application (2023-2212) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone for field uses and for all MSs of the European Union for uses under protection, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of PYGMALION (DSPF016) has been made using endpoints agreed in the EU peer review of potassium phosphonates. It also includes assessment of data and information related to PYGMALION (DSPF016) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

¹ Commission Implementing Regulation (EU) No 369/2013 of 22 April 2013 approving the active substance potassium phosphonates, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

² REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

³ SANCO document "risk envelope approach", European Commission (14 March 2011). [Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5](#)

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

This document also describes the specific conditions of use and labelling required for France for the registration of PYGMALION.

1.2 Letters of Access

The active substance “Potassium Phosphonates” are not protected any more.

The applicant has provided letters of access for PPP data. These letters of access are available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: “Several new studies have been performed with PYGMALION (DSPF016) in order to complete the data package on PYGMALION (DSPF016), due to the not EU approved uses in wheat, and potato, lettuce and various minor crops (use No 4 – 19) (summarized in the table presented in chapter 2.6).”

1.4 Data protection claims

2 Where protection for data is being claimed for information supporting registration of PYGMALION (DSPF016), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. Details of the authorisation decision

2.1 Product identity

Product code	DSPF016
Product name in MS	PYGMALION
Authorisation number	2210128
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	DE SANGOSSE
Active substance(s) (incl. content)	755 g/L Potassium Phosphonates
Formulation type	Soluble concentrate [SL]
Packaging	Packaging not changed
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

Recommended tank mixtures	None
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2.2 Conclusion

The evaluation of the application for PYGMALION (DSPF016), resulted in the decision **to grant** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

Classification not changed.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁵ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

⁵ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ is to supply “minor” crops with registered plant protection products.

Therefore, the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021⁸ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 1	To protect frugivorous mammals, do not apply after BBCH stage 69 for uses seed crops production (perfume, aromatic, medicinal, condiment and vegetable plants).
Spe 2	For uses in permanent greenhouses: To protect aquatic organisms, do not discharge waste water from soil-less greenhouses directly into surface water.

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

⁷ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

⁸ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 m meters with an unsprayed vegetated buffer zone of 5 meters to surface water bodies for uses on open field ornamentals trees and bush and rosebush. ⁹
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 m meters to surface water bodies for uses on ornamentals trees and bush and rosebush under walk-in tunnel if open during treatment.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 m meters with an unsprayed vegetated buffer zone of 5 meters to surface water bodies for uses on open field lettuce, lamb's lettuce, spinaches and similar leaves, herbs and edible flowers, artichokes, poppy, seed crops production (perfume, aromatic, medicinal, condiment and vegetable plants), seed crops production (industrial and fodder sugar beet), seed crops production (grasses forage), tobacco, ornamental and floral crops. ¹⁰
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies for uses on lettuce, lamb's lettuce, spinaches and similar leaves, herbs and edible flowers, ornamental and floral crops under walk-in tunnel if open during treatment.
SPe 8	May be dangerous to bees. Application is possible when in flower and on foraging areas according to the conditions set by the French Order of 20 November 2021 (refer to the Decision in Appendix 1 for the details).
Precautionary phrase	For uses in permanent greenhouses: May affect pollinators. Avoid unnecessary exposure.
Other specific restrictions	
Re-entry period	6 hours outdoor and 8 hours indoor.
Storage	-
Risk mitigation measures	Several fungicidal active substances (fosetyl-Al, potassium phosphonates and disodium phosphonate) may lead to the presence of phosphonic acid in harvested products. The cumulated uses of these active substances on the same crop might lead to an exceedance of the MRL set jointly for these 3 active substances.
Risk mitigation measures	Buffer zone: 3 for low crops and 10 m for high crops.

The other conditions of use specified in the previous evaluations are not changed.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

⁹ The unsprayed vegetated buffer zone is applied in order to limit risk from eutrophication and to protect aquatic organisms.

¹⁰ The unsprayed vegetated buffer zone is applied in order to limit risk from eutrophication.

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as izRMS. Those uses are then granted in France.

When the conclusion is "not acceptable" the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date 23/10/2025

PPP (product name/code): **PYGMALION/DSPF016**

Formulation type: SL ^(a, b)

Active substance 1: Potassium phosphonates

Conc. of a.s. 1: 755 g/L ^(c)

Applicant: DE SANGOSSE

Professional use: ☒

Zone(s): Zonal (southern) and Interzonal ^(d)

Non-professional use:

Verified by MS: Yes

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method/Kind	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3	South Zone (FR)	Lettuce	Fl	Downy Mildew (<i>Bremia</i> BREMSp, <i>Peronospora</i> PEROSP) <i>sp.</i> <i>sp.</i>	Foliar application, using a sprayer & Motor knapsack and hand sprayer	From BBCH 11	a) 2 b) 2 per crop / 5 per year	7	a) 3.5 L/ha b) 7 L / 17.5 L/ha	a) 2642.5 (1764) b) 5285 (3528) / 13212.5 (8820)	Max 1000	14	Acceptable

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method/Kind	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
3	South Zone (FR)	Lettuce	G	Downy Mildew (<i>Bremia</i> sp. BREMSp, <i>Peronospora</i> sp. PEROSP)	Foliar application, using a sprayer & Motor knapsack and hand sprayer	From BBCH 11	a) 2 b) 2 per crop / 5 per year	7	a) 3.5 L/ha b) 7 L / 17.5 L/ha	a) 2642.5 (1764) b) 5285 (3528) / 13212.5 (8820)	Max 1000	14	Acceptable
Minor uses according to Article 51 (interzonal uses)													
4	South Zone (FR)	Lamb's lettuce, cornsalads, escarole/broadleaved endive, cresses and other sprouts and shoots, land cress (<i>Barbarea verna</i>), garden cress (<i>Lepidium sativum</i>), roman rocket/rucola, red/brown mustard, baby-leaf crops (including <i>Brassica</i> species), others	F	Downy Mildew (<i>Bremia</i> sp. BREMSp <i>Peronospora</i> sp. PEROSP)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 11 Up to PHI	a) 2 b) 2 per crop / 5 per year	7	a) 3.5 L/ha b) 7 L / 17.5 L/ha	a) 2642.5 (1764) b) 5285 (3528) / 13212.5 (8820)	Max 1000	14	Acceptable

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method/Kind	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
4	South Zone (FR)	Lamb's lettuce, cornsalads, escarole/broadleaved endive, cresses and other sprouts and shoots, land cress (<i>Barbarea verna</i>), garden cress (<i>Lepidium sativum</i>), roman rocket/rucola, red/brown mustard, baby-leaf crops (including <i>Brassica</i> species), others	G	Downy Mildew (<i>Bremia sp</i> BREMSP I, <i>Peronospora sp.</i> PEROSP)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 11	a) 2 b) 2 per crop / 5 per year	7	a) 3.5 L/ha b) 7 L / 17.5 L/ha	a) 2642.5 (1764) b) 5285 (3528) / 13212.5 (8820)	Max 1000	14	Acceptable
5	South Zone (FR)	Spinaches and similar leaves (Spinaches, Purslanes, Chards/beet leaves, Other spinach and similar)	F	Downy mildew (<i>Peronospora</i> <i>farinosa f. sp.</i> <i>Spinaciae</i> PEROFS)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 11	a) 2 b) 2 per crop / 5 per year	7	a) 3.5 L/ha b) 7 L / 17.5 L/ha	a) 2642.5 (1764) b) 5285 (3528) / 13212.5 (8820)	Max 1000	14	Acceptable
5	South Zone (FR)	Spinaches and similar leaves	G	Downy mildew (<i>Peronospora</i> <i>farinosa f. sp.</i> <i>Spinaciae</i> PEROFS)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 11 Up to PHI	a) 2 b) 2 per crop / 5 per year	7	a) 3.5 L/ha b) 7 L / 17.5 L/ha	a) 2642.5 (1764) b) 5285 (3528) / 13212.5 (8820)	Max 1000	14	Acceptable
6	South Zone (FR)	Herbs and edible flowers	F	Downy Mildew (<i>Peronospora sp.</i> PEROSP, <i>Plasmopara sp.</i> PLASSP)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 11	a) 2 b) 2 per crop / 5 per year	7	a) 3.5 L/ha b) 7 L / 17.5 L/ha	a) 2642.5 (1764) b) 5285 (3528) / 13212.5 (8820)	Max 1000	14	Acceptable

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method/Kind	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
6	South Zone (FR)	Herbs and edible flowers	G	Downy Mildew (<i>Peronospora</i> sp. <i>PEROSP</i> , <i>Plasmopara</i> sp. <i>PLASSP</i>)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 11	a) 2 b) 2 per crop / 5 per year	7	a) 3.5 L/ha b) 7 L / 17.5 L/ha	a) 2642.5 (1764) b) 5285 (3528) / 13212.5 (8820)	Max 1000	14	Acceptable
7	South Zone (FR)	Artichokes	F	Downy Mildew (<i>Bremia lactucae</i> BREMLA)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 12	a) 2 b) 2	7	a) 3.5 L/ha b) 7 L/ha	a) 2642.5 (1764) b) 5285 (3528)	Max 1000	21	Acceptable
8	South Zone (FR)	Poppy (including <i>Papaver rhoeas</i> , <i>Papaver somniferum</i> , <i>Epilobium hirsutum</i> , and non-edible perfume, aromatic and medicinal plants)	F	Downy Mildew (<i>Peronospora arborescens</i> PEROAR)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 12	a) 2 b) 2	10	a) 3.5 L/ha b) 7 L/ha	a) 2642.5 (1764) b) 5285 (3528)	Max 1000	21	Acceptable
10	South Zone (FR)	Seed crops production: perfume plants, aromatic plants, medicinal plants, condimental plants, flower plants and vegetable plants	F	Downy mildew and white rust (<i>Albugo</i> sp. ALBUSP, <i>Bremia</i> sp. BREMSP, <i>Peronospora</i> sp. PEROSP, <i>Plasmopara</i> sp. PLASSP, <i>Pseudoperonospora</i> sp PSPESP, ...)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 12 Until BBCH 69	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method/Kind	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
11	South Zone (FR)	Seed crops production: perfume plants, aromatic plants, medicinal plants, condimental plants, flower plants and vegetable plants	F	Leaf diseases: leaf spot (<i>Alternaria</i> sp. ALTESP, <i>Ascochyta</i> sp. ASCOSP, <i>Cercospora</i> sp. CERCSP, <i>Colletotrichum</i> sp. COLLSP, <i>Ramularia</i> sp. RAMUSP, <i>Septoria</i> sp. SEPTSP, <i>Stemphylium</i> sp. STEMSP, ...)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 12 Until BBCH 69	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable
12	South Zone (FR)	Seed crops production: Industrial and fodder sugar beet	F	Downy mildew (<i>Peronospora</i> sp PEROSP)	Foliar application, using a sprayer	From BBCH 12 Until BBCH 85	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable
13	South Zone (FR)	Seed crops production: Industrial and fodder sugar beet	F	Leaf diseases: leaf spot (<i>Alternaria</i> sp. ALTESP, <i>Cercospora</i> sp. CERCSP, <i>Peronospora</i> sp. PEROSP, <i>Phoma</i> sp. PHOMSP, <i>Puccinia</i> sp. PUCCSP, <i>Ramularia</i> sp. RAMUSP, ...)	Foliar application, using a sprayer	From BBCH 12 Until BBCH 85	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or and/ situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method/Kind	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
14	South Zone (FR)	Seed crops production: Grasses forage	F	Leaf diseases (<i>Helminthosporium</i> <i>sp.</i> <i>Mastigosporium sp.</i> <i>Rhynchosporium sp.</i> <i>Scolicotrichum sp.</i>)	Foliar application, using a sprayer	From BBCH 30 Until BBCH 85	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable
15	South Zone (FR)	Tobacco	F	Downy mildew (<i>Peronospora</i> <i>tabacina</i> PEROTA)	Foliar application, using a sprayer	From BBCH 29 Until BBCH 59	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable
16	South Zone (FR)	Ornamental trees and shrubs	F	Downy mildew (<i>Peronospora</i> <i>sp.</i> PEROSP, <i>Phytophthora sp</i> PHYTSP, <i>Plasmopara</i> <i>sp.</i> PLASSP)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 10 Until BBCH 89	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable
16	South Zone (FR)	Ornamental trees and shrubs	G	Downy mildew (<i>Peronospora</i> <i>sp.</i> PEROSP, <i>Phytophthora sp</i> PHYTSP, <i>Plasmopara</i> <i>sp.</i> PLASSP)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 10 Until BBCH 89	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method/Kind	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
17	South Zone (FR)	Ornamentals and floral crops	F	Downy mildew (<i>Basidiophora entospora</i> BASIEN, <i>Bremia sp.</i> BREMSP, <i>Bremiella megasperma</i> BRLLME, <i>Peronospora sp.</i> PEROSP, <i>Plasmopara sp.</i> PLASSP)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 10 Until BBCH 89	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable
17	South Zone (FR)	Ornamentals and floral crops	G	Downy mildew (<i>Basidiophora entospora</i> BASIEN, <i>Bremia sp.</i> BREMSP, <i>Bremiella megasperma</i> BRLLME, <i>Peronospora sp.</i> PEROSP, <i>Plasmopara sp.</i> PLASSP)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 10 Until BBCH 89	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable
18	South Zone (FR)	Rosebush	F	Downy mildew (<i>Peronospora sparsa</i> PSPESR)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 10 Until BBCH 89	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f) RMS CONCLUSION
					Method/Kind	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
18	South Zone (FR)	Rosebush	G	Downy mildew (<i>Peronospora sparsa</i> PSPEER)	Foliar application, using a sprayer & Motor Knapsack and hand sprayer	From BBCH 10 Until BBCH 89	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable
19	South Zone (FR)	Seed crops production: Grasses forage	F	Rust (<i>Puccinia sp PUCCSP</i>)	Foliar application, using a sprayer	From BBCH 30 Until BBCH 85	a) 5 b) 5	7	a) 4 L/ha b) 20 L/ha	a) 3020 (2016) b) 15080 (10080)	Max 1000	n.a.	Acceptable

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.

** The application is possible during the flowering period in line with the application of the French Order of November 20, 2021 (arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques).

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

The physico-chemical properties of the formulation have been evaluated and considered acceptable during the first registration of the product. The intended concentrations claimed for the extension use(s) (concentrations from 0.35-0.4% v/v) are covered by the concentrations authorized during the registration of this formulation.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

For use against downy mildews in lettuce, the effectiveness level of PYGMALION is considered acceptable for the use requested on downy mildew of lettuce.

For minor uses eligible to the application of Article 51 of Regulation (EC) No 1107/2009, verification of the effectiveness and the absence of possible risks of phytotoxicity on these crops is not necessary.

The phytotoxicity level of PYGMALION is considered negligible for the requested use on lettuce.

The risks of negative impact on yield, quality, propagation, succeeding and adjacent crops are considered negligible.

The risk of resistance to potassium phosphonates does not require a monitoring.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of the active substance in the formulation is available and validated. As the active substance potassium phosphonates does not contain relevant impurity, no analytical method is required.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of potassium phosphonates in plants (potato), food of animal origin, soil, water (surface and drinking).

Methods for pre-registration (stability study – poppy seed and honey) are validated. However, methods to support residues trials (magnitude) are not validated as extraction efficiency is missing. Please refer to RR Section 5.

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance	Potassium phosphonates
AOEL systemic	5 mg/kg bw/day
AAOEL	-
Oral absorption	100%
Vapour pressure	100%
Reference	EFSA 2012; 10 (12):2963
Dermal absorption	Concentrate: 0.24% Dilution (1:400): 2.6%

3.4.1 Acute toxicity

PYGMALION containing 755 g/L potassium phosphonate has a low oral, dermal and inhalation toxicity, is not irritating to skin or to the eye and is not a skin sensitizer.

3.4.2 Operator exposure

	Considering proposed uses, operator systemic exposure was estimated using the French study from EFSA model ¹¹ :		
	Long term exposure		
	Model data	Level of PPE	% of systemic AOEL
	Outdoor		
	Critical use: high ornamentals		
	Application rate: 5* 3.02 kg a.s. /ha		
	Upward application		
	Vehicle mounted		
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg		
		Work wear (arms, body and legs covered)	1.0
Manual handheld			

¹¹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2022;20(1):7032)

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

	Spray application (AOEM; 75 th percentile) Body weight: 60 kg			
		Work wear (arms, body and legs covered)		0.5
	Manual knapsack			
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg			
		Work wear (arms, body and legs covered)		0.2
	Outdoor <u>Critical use:</u> low ornamentals Application rate: 5*3.02 kg a.s. /ha downward application			
	Vehicle mounted			
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg			
		Work wear (arms, body and legs covered)		0.4
	Manual handheld			
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg			
		Work wear (arms, body and legs covered)		0.8
	Manual knapsack			
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg			
		Work wear (arms, body and legs covered)		0.2
	Indoor <u>Critical use:</u> high ornamentals Application rate: 5* 3.02 kg a.s. /ha Upward application			
	Dense scenario, Manual handheld			

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

	Spray application (AOEM; 75 th percentile) Body weight: 60 kg			
		Work wear (arms, body and legs covered)		19.1
	Dense scenario, Manual knapsack			
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg			
		Work wear (arms, body and legs covered)		19.1
	Normal scenario, Manual-Trolley			
	Spray application (AOEM; 75 th percentile) Body weight: 60 kg			
		Work wear (arms, body and legs covered)		0.6
According to the exposure assessment using EFSA 2022 model, operator exposure to DSPF016 is below the AOELvalue of active substance.				
For details of personal protective equipment for operators, refer to the Decision in Appendix 1.				

3.4.3 Worker exposure

	<p>Workers may have to enter into treated areas after treatment for crop inspection/irrigation or cutting, sorting, bundling, carrying or hand harvesting or maintenance or reaching, picking or searching, reaching, picking activities. Therefore, estimation of worker exposure was calculated according to AOEM model.</p>			
	Model data	Level of PPE		% of systemic AOEL
	<p>Outdoor <u>Critical use:</u> tobacco (viticulture) Application rate: 5*3.02 kg a.s./ha Hand-harvesting Work rate: 8 hours/day DT50: 30 days DFR: 3 µg/cm²/kg a.s./ha</p>			

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

Interval between treatments: 7 days			
Spray application Body weight: 60 kg			
	Work wear – arms, body and legs covered TC: 10100 cm ² /h		23.5%
Outdoor <u>Critical use:</u> ornamentals (high and low) Application rate: 5*3.02 kg a.s./ha Cutting, sorting, bundling, carrying Work rate: 8 hours/day DT50: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Spray application Body weight: 60 kg			
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm ² /person/h		3.3%
Indoor <u>Critical use:</u> ornamentals (high and low) Application rate: 5*3.02 kg a.s./ha Cutting, sorting, bundling, carrying/harvesting, including, cutting, and bundling Work rate: 8 hours/day DT50: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Spray application Body weight: 60 kg			
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm ² /person/h		4.1%
Outdoor <u>Critical use:</u> low vegetable (sugar beet) Application rate: 5*3.02 kg a.s./ha Bolting beet removal Work rate: 8 hours/day DT50: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Spray application Body weight: 60 kg			
	Work wear (arms, body and legs covered) and gloves TC: 430 cm ² /person/h		1%

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

	According to the exposure assessment using the EFSA model 2022, worker exposure to DSPF016 is below the AOEL value of the active substance with a working coverall and gloves.
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3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹². Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2022;20(1):7032): “No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”

3.4.5 Resident exposure

Resident exposure was assessed according to EFSA model without mitigation measures.			
Model data			% of systemic AOEL
Outdoor Critical use: low ornamentals Buffer zone: 2-3 m Drift reduction technology: no Interval between treatments: 7 days DT50: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Application rate		5*3.02 kg a.s./ha	
Resident adult Body weight: 60 kg	Spray drift (75 th perc.)		0.01
	Vapour (75 th perc.)		0.005
	Surface deposits (75 th perc.)		0.04
	Re-entry (75 th perc.)		0.5
	Sum (mean)		0.5
Resident childre Body weight:	Spray drift (75 th perc.)		0.04
	Vapour (75 th perc.)		0.02

¹² Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

		10 kg	Surface deposits (75 th perc.)		0.3
			Re-entry (75 th perc.)		1
			Sum (mean)		1
		Outdoor Critical use: high ornamentals Buffer zone: 10 m Drift reduction technology: no Interval between treatments: 7 days DT50: 30 days DFR: 3 µg/cm ² /kg a.s./ha			
		Application rate		5*3.02 kg a.s./ha	
		Resident adult Body weight: 60 kg	Spray drift (75 th perc.)		0.1
			Vapour (75 th perc.)		0.005
			Surface deposits (75 th perc.)		0.007
			Re-entry (75 th perc.)		0.5
			Sum (mean)		0.5
		Resident children Body weight: 10 kg	Spray drift (75 th perc.)		0.2
			Vapour (75 th perc.)		0.02
			Surface deposits (75 th perc.)		0.05
			Re-entry (75 th perc.)		1
			Sum (mean)		1
		Indoor Critical use: low ornamentals Buffer zone: 2-3 m Drift reduction technology: no Interval between treatments: 7 days DT50: 30 days DFR: 3 µg/cm ² /kg a.s./ha			
		Application rate		5*3.02 kg a.s./ha	
		Resident adult Body weight: 60 kg	Spray drift (75 th perc.)		0.01
			Vapour (75 th perc.)		0.005
			Surface deposits (75 th perc.)		0.04
			Re-entry (75 th perc.)		NA
			Sum (mean)		0.04
		Resident children Body weight: 10 kg	Spray drift (75 th perc.)		0.04
			Vapour (75 th perc.)		0.02
			Surface deposits (75 th perc.)		0.3
			Re-entry (75 th perc.)		NA
			Sum (mean)		0.2
		Indoor Critical use: high ornamentals Buffer zone: 10 m Drift reduction technology: no Interval between treatments: 7 days DT50: 30 days			

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

	DFR: 3 µg/cm ² /kg a.s./ha			
	Application rate		5*3.02 kg a.s./ha	
	Resident adult Body weight: 60 kg	Spray drift (75 th perc.)		0.1
		Vapour (75 th perc.)		0.005
		Surface deposits (75 th perc.)		0.007
		Re-entry (75 th perc.)		NA
		Sum (mean)		0.09
	Resident children Body weight: 10 kg	Spray drift (75 th perc.)		0.2
		Vapour (75 th perc.)		0.02
		Surface deposits (75 th perc.)		0.05
		Re-entry (75 th perc.)		NA
		Sum (mean)		0.2
	According to the exposure assessment performed by EFSA model, resident exposure to DSPF016 is below the AOEL value of substance active, without mitigation measures.			

3.5 Residues and consumer exposure (Part B, Section 7)

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for active substance as laid down in Reg. (EU) 396/2005 is not expected.

Tobacco, seed for crop production (poppy seeds, perfume plants, aromatic plants, medicinal plants, condimental plants, flower plants and vegetable plants, industrial and fodder sugar beet, grasses forage), ornamental trees and shrubs, ornamentals and floral crops and rosebush (pot plants, cut flowers, forced shrubs and cut green), chrysanthemum, hibiscus, rose, china rose, dahlia, carnation, mallow, flower bulb and flower tuber crops (amaryllis, dahlia, gladiolus, hyacinth, lily, narcissus, tulip, iris, crocus, other flower bulbs and tubers), other floral and ornamental crops, nurseries of ornamentals and floral crops, ornamentals hardy nursery stock are non-edible commodities. No further assessment was carried out for these crops.

The chronic intakes of potassium phosphonates residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France, zRMS, agrees with the authorization of the intended uses.

According to available data, specific mitigation measures are recommended.

Summary for DSPF016 (PYGMALION) (KCA 6.8)

Crop	PHI for DSPF016 (PYGMALION) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for DSPF016 (PYGMALION) proposed by zRMS	zRMS Comments (if different PHI proposed)
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DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

		Potassium Phosphonates		
Lettuce	14 days	Yes	14 days	-
Lamb's lettuce/ cornsalads, Escaroles/broad- leaved endives, Cresses and sprouts and shoots, Land cresses, Roman rocket/rucola, Red/brown mustards, Baby leaf crops (including Brassica species), Others	14 days	Yes	14 days	
Spinaches and similar leaves (Spinaches)	14 days	Yes	14 days	-
Spinaches and similar leaves (Purslanes, Chards/beet leaves, Other spinach and similar)	14 days	Yes	14 days	
Herbs and edible flowers	14 days	Yes	14 days	-
Artichokes	21 days	Yes	21 days	
Poppy	21 days	Yes	21 days	
Ornamentals trees and shrubs Ornamentals and floral crops Rosebush Flower bulb and flower tuber crops Other floral and ornamental crops Nurseries of ornamentals and floral crops. Ornamentals Hardy	NR	NR	NR	Non edible commodities
Tobacco	NR	NR	NR	Non edible commodities
Seed for crop production	NR	NR	NR	Non edible commodities Only for seed production

NR: not relevant

* Purpose of withholding period to be specified

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

zRMS notes that in the absence of any submitted izRR covering GAPs under greenhouses, conclusions will be made for these structures based on the exposure assessment proposed within this zonal dRR. It is up to cMS to draw their own conclusions.

For the present dossier, the applicant provided a full open field evaluation for all environmental compartments, and this is considered to be conservative to cover the intended uses under walk-in tunnel and all other non-permanent, open or permeable structures to be evaluated at zonal level.

For the intended uses under greenhouses with soil-less culture, exposure of environmental compartments to the active substance is considered negligible. Consequently, no risk assessment for environment is deemed necessary.

For the intended uses in open field, under greenhouse with soil-bound culture and under walk-in tunnel and all other non-permanent, open or permeable structures the PEC of phosphonic acid in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PEC_{sw} derived for the active substance are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} for phosphonic acid do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for aquatic organisms, mammals, non-target arthropods other than bees, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5.

For birds, the risk is acceptable at Tier 1 for intended uses on open-field and under tunnels except for uses tobacco, lettuce and similar uses, poppy, seed crops production (PPAMC, flower plants and vegetables plant and grasses forage), ornamental trees and shrub, and ornamentals and floral crops.

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document. The risks are not acceptable at Tier 1 for all intended uses for adults (acute and chronic) and larvae. A higher-tier study (semi-field) conducted with the product PYGMALION provided by the applicant to refine the risk assessment demonstrates that no adverse effects are expected on brood. However, this study was not considered sufficient to demonstrate the absence of unacceptable effects of the product on adult bees. In particular, the toxic reference used is an insect growth regulator, which does not allow to confirm the sensitivity of adult bees.

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

Therefore, the risk assessment for honey bee adults cannot be finalized for all intended uses except for uses in permanent greenhouses.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance potassium phosphonates is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

Appendix 1 Copy of the product authorisation



Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

FACES VISIBLES

PYGMALION®

Fongicide pour le traitement contre le mildiou de la pomme de terre, la septoriose du blé
et autres cultures maraichères et porte-graines
(voir détail des cultures autorisées dans le tableau des usages)

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Concentré soluble (SL)
755 g/L de phosphonates de potassium (51.7 %)
(504 g/L d'équivalent d'acide phosphonique)


AMM n° 2210128

Détenteur de l'AMM, distributeur, EMB et marque déposée :

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BONNEL - CS10005
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France
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Bien lire l'étiquette avant toute utilisation et respecter les précautions d'emploi

<p>Code version étiquette</p> <p>Réemploi de l'emballage interdit</p> <p>Consulter ce livret avant toute utilisation</p>	
<p>N° de lot/date de fabrication : voir sur l'emballage</p> <p>- Code barre (code EAN) - 2D Datamatrix</p>	

PYGMALION®

AMM n° 2210128

Contient 755 g/L (51.7%) de phosphonates de potassium (504 g/L d'équivalent d'acide phosphonique)

P102 : Tenir hors de portée des enfants

P270 : Ne pas manger, boire ou fumer en manipulant ce produit

P280 : Porter des gants de protection / des vêtements de protection

P501 : Eliminer le contenu/le récipient conformément à la réglementation locale/nationale

EUH401 : Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement

SP1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 10 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 10 mètres en bordure des points d'eau pour l'usage « Arbres et arbustes ».

SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour tous les autres usages.

SPe8 : Pour protéger les abeilles et autres insectes pollinisateurs, ne pas utiliser en présence d'abeilles et autres insectes pollinisateurs, ne pas appliquer durant la période de floraison.

Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 5 mètres pour l'usage « Arbres et arbustes », et de 3 mètres pour les autres usages, entre la rampe de pulvérisation et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Délai de rentrée dans les cultures (DRE) : 6 heures

EN CAS D'URGENCE**Composer le 15 ou le 112 ou contacter le centre anti poison le plus proche**

Puis signaler vos symptômes au réseau Phyt'Attitude, N° Vert : 0 800 887 887 (appel gratuit depuis un poste fixe).

PREMIERS SOINS :

S'éloigner de la zone dangereuse

En cas de contact cutané : Rincer la peau immédiatement avec de l'eau et du savon. Retirer les vêtements contaminés et les laver avant réutilisation. Contacter le centre anti poison ou un médecin pour obtenir des conseils de traitement.

En cas de contact avec les yeux : Garder les paupières ouvertes et rincer doucement et délicatement avec de l'eau pendant 15-20 minutes. Oter les lentilles de contact, le cas échéant, après les 15 premières minutes, puis continuer à rincer les yeux. Si l'irritation persiste, consulter un médecin.

En cas d'inhalation: Déplacer la victime et l'amener à l'air frais. Si la personne a du mal à respirer ou ne respire plus, contacter immédiatement un médecin.

En cas d'ingestion: Consulter immédiatement un médecin et lui montrer l'étiquette et/ou la fiche de données de sécurité. Ne pas faire vomir sauf avis contraire du centre anti poison ou du médecin.

Ne rien administrer oralement à une personne inconsciente.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

En cas d'intoxication animale, contactez votre vétérinaire

Fiche de Données de Sécurité disponible sur www.quickfds.com

LIVRET

DESCRIPTIF DU PRODUIT

PYGMALION® est un fongicide systémique à action préventive contre différents pathogènes, notamment la septoriose du blé (*Zymoseptoria tritici*), le mildiou de la pomme de terre (*Phytophthora infestans*) et autres mildious (*Bremia*, *Peronospora*). PYGMALION® est reconnu comme un produit de biocontrôle : sa matière active, le phosphonate de potassium, est une substance naturelle d'origine minérale.

• Tableau des usages autorisés - Pour un traitement des parties aériennes

Cultures	Cibles	Dose maximum d'emploi*	Stades d'application	Nombre maximum d'applications	Intervalle minimum entre les applications	Délai avant récolte (DAR)	Zone Non Traitée aquatique (mètres)
Blé <i>Portée de l'usage :</i> Triticale, Epeautre, Tritordeum et autres hybrides du blé	Septoriose(s) (<i>Zymoseptoria tritici</i>)	4 L/ha	BBCH 25-59	2 / an	23 jours	BBCH 59 maximum	5 (dont DVP 5)
Pomme de terre	Mildiou(s) (<i>Phytophthora infestans</i>)	4 L/ha	A partir du stade BBCH 10 (développement des feuilles)	3 / an	7 jours	7 jours	5 (dont DVP 5)
Laitue** <i>Toute la portée de l'usage :</i> Chicorée - Scarole, Chicorée - Frisée A, Mâche, Roquette et autres Salades	Mildiou(s) (<i>Bremia sp.</i> , <i>Peronospora sp.</i>)	3.5 L/ha	A partir du stade BBCH 11	2 / cycle cultural 5 / an (sur 3 cycles)	7 jours	14 jours	5 (dont DVP 5)

DVP : Dispositif Végétalisé Permanent

* Pour les doses recommandées se reporter à la section « Conditions d'application »

** plein champ et sous abris

DE SANGOSSE ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, décline toute responsabilité concernant son utilisation aux autres usages prévus par le catalogue des usages en vigueur.

Pour les usages mentionnés ci-dessous, les extensions d'autorisation ont été obtenues dans le cadre de l'article 51 du règlement (CE) n° 1107/2009 (extension des autorisations de mise en marché pour les utilisations mineures). L'attention de l'utilisateur est attirée sur les risques éventuels de phytotoxicité ou de manque d'efficacité. Au regard des données à sa disposition, DE SANGOSSE décline toute responsabilité sur ces éventuels risques.

Avant tout emploi du produit, il est recommandé à l'utilisateur de s'assurer de son efficacité ou de l'absence de risques éventuels de phytotoxicité sur la culture.

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

Cultures	Cibles	Dose maximum d'emploi*	Stades d'application	Nombre maximum d'applications	Intervalle minimum entre les applications	Délai avant récolte (DAR)	Zone Non Traitée aquatique (mètres)
Artichaut <i>Toute la portée de l'usage : Cardon</i>	Mildiou(s) (<i>Bremia lactucae.</i>)	3.5 L/ha	A partir du stade BBCH 12	2 / an	7 jours	21 jours	5 (dont DVP 5)
Cresson alenois** Cresson de terre**	Mildiou(s) (<i>Peronospora sp.</i>)	3.5 L/ha	A partir du stade BBCH 11	2 / cycle cultural 5 / an (sur 3 cycles)	7 jours	14 jours	5 (dont DVP 5)
Epinard** <i>Toute la portée de l'usage : Feuilles de Bettes, Pourpier</i>	Mildiou(s) (<i>Peronospora farinosa f. sp. Spinaciae</i>)	3.5 L/ha	A partir du stade BBCH 11	2 / cycle cultural 5 / an (sur 3 cycles)	7 jours	14 jours	5 (dont DVP 5)
Fines herbes** <i>Toute la portée de l'usage, dont : Plantes alliées dont Ciboulette. Plantes apiacées dont Aneth, Persil, Cerfeuil, Feuilles de Fenouil, Angélique, Carvi. Plantes astéracées dont Estragon, Stevia. Plantes lamiacées dont Basilic, Thym, Sauge, Sarriette, Origan, Marjolaine, Hysop, Menthe. Autres plantes condimentaires, fines herbes consommées fraîches, fleurs comestibles et PPAM non alimentaires.</i>	Mildiou(s) (<i>Peronospora sp., Plasmopara crustosa (nivea), Peronospora belbahrii., Plasmopara sp.</i>)	3.5 L/ha	A partir du stade BBCH 11	2 / cycle cultural 5 / an (sur 3 cycles)	7 jours	14 jours	5 (dont DVP 5)
Pavot <i>Portée de l'usage : Oeillet, Onagre, ainsi que les PPAM non alimentaires</i>	Mildiou(s) (<i>Peronospora arborescens.</i>)	3.5 L/ha	A partir du stade BBCH 12	2 / an	10 jours	21 jours	5 (dont DVP 5)
Porte graine - PPAMC Florales Potagères** <i>Toute la portée de l'usage : Toute plante destinée à la production de semences de PPAMC, de cultures florales ou de cultures potagères</i>	Mildiou(s) et rouille blanche Maladies des taches foliaires (<i>Albugo sp., Bremia sp., Peronospora sp., Plasmopara sp., Pseudoperonospora sp., ...</i>) (<i>Alternaria sp., Ascochyta sp., Cercospora sp.,</i>	4 L/ha	BBCH 12-85	5 / an	7 jours	BBCH 85 maximum	5 (dont DVP 5)

DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

	<i>Colletotrichum</i> sp., <i>Ramularia</i> sp., <i>Septoria</i> sp., <i>Stemphylium</i> sp., ...)						
Porte graine - Betterave industrielle et fourragère <i>Toute la portée de l'usage :</i> Porte-graine de Betterave à sucre, betterave fourragère	Mildiou(s) Maladies des taches foliaires (<i>Peronospora</i> sp.) (<i>Alternaria</i> sp., <i>Cercospora</i> sp., <i>Peronospora</i> sp., <i>Phoma</i> sp., <i>Puccinia</i> sp., <i>Ramularia</i> sp., ...)	4 L/ha	BBCH 12-85	5 / an	7 jours	BBCH 85 maximum	5 (dont DVP 5)
Porte graine - Graminées fourragères et à gazons <i>Toute la portée de l'usage :</i> Porte-graine de Brome, Dactyle, Fétuque(s), Pâturin, Ray grass, et autres espèces de graminées fourragères	Maladies des taches foliaires Rouilles (<i>Helminthosporium</i> sp., <i>Mastigosporium</i> sp., <i>Rhynchosporium</i> sp., <i>Scolicotrachum</i> sp.) (<i>Puccinia</i> sp.)	4 L/ha	BBCH 30-85	5 / an	7 jours	BBCH 85 maximum	5 (dont DVP 5)
Tabac	Mildiou(s) (<i>Peronospora tabacina</i>)	4 L/ha	BBCH 29-59	5 / an	7 jours	BBCH 59 maximum	5 (dont DVP 5)
Arbres et arbustes** <i>Portée de l'usage :</i> Toutes espèces ligneuses de feuillus et résineux produites en A Pépinières ornementales et forestières, peupleraies, oseraies, palmeraies, plantations de sapins de Noël, vergers à graines, feuillage et rameaux coupés, suberaies cultivées, truffières artificielles, boisement de terrains agricoles, taillis à courte et à très courte révolution, ainsi que les semis et plantations forestières de moins de 3 mètres de hauteur moyenne. Couvre également l'entretien de ces espèces en JEVI.	Mildiou(s) (<i>Peronospora</i> sp., <i>Phytophthora</i> sp., <i>Plasmopara</i> sp.)	4 L/ha	BBCH 10-89	5 / an	7 jours	BBCH 89 maximum	10 (dont DVP 10)
Cultures florales et plantes vertes**	Mildiou(s)	4 L/ha	BBCH 10-89	5 / an	7 jours	BBCH 89 maximum	5

<p><i>Portée de l'usage :</i> Toutes espèces de plantes herbacées vivaces ou annuelles cultivées en plein air ou sous abris: potées fleuries, plantes à massifs, fleurs et feuillages coupés, pieds-mères en production, jeunes plants et boutures, y compris bulbes ornementaux pendant leur phase végétative, mini rosiers en potée fleurie. Couvre également l'entretien de ces espèces en JEVI.</p>	<p>(<i>Basidiophora entospora</i>, <i>Bremia sp.</i>, <i>Bremiella megasperma</i>, <i>Peronospora sp.</i>, <i>Plasmopara sp.</i>)</p>						(dont DVP 5)
<p>Rosiers**</p> <p><i>Portée de l'usage :</i> Toutes espèces et cultivars du genre <i>Rosa</i> : rosier pour la fleur coupée, rosier de pépinière, incluant les porte-greffes. Couvre également l'entretien de ces espèces en JEVI.</p>	<p>Mildiou(s) (<i>Peronospora sparsa</i>)</p>	4 L/ha	BBCH 10-89	5 / an	7 jours	BBCH 89 maximum	5 (dont DVP 5)

DVP : Dispositif Végétalisé Permanent

** plein champ et sous abris

Limites Maximales de Résidus : se reporter aux LMR du fosétyl-Al définies au niveau de l'Union Européenne
<http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>

• Mode d'action

Les phosphonates de potassium, contenus dans PYGMALION®, présentent une efficacité directe sur les pathogènes, ainsi qu'une action indirecte par la stimulation des défenses naturelles de la plante. Cette substance active est systémique et se répartit dans l'ensemble de la plante après pénétration via le système foliaire. Ainsi, PYGMALION® assure une très bonne protection des organes néoformés dans le cadre de nos recommandations d'emploi.

RECOMMANDATIONS D'EMPLOI

• Conditions d'application

PYGMALION® doit être appliqué en préventif. Reportez-vous aux observations et/ou au BSV de votre région pour déclencher les traitements.

Il est conseillé d'alterner les différentes familles chimiques durant la saison pour limiter le risque d'apparition de résistance.

PYGMALION® est associé au groupe FRAC P07 présentant un très faible risque d'apparition de résistance.

PYGMALION® apporte un nouveau mode d'action pour la gestion de la résistance de la septoriose du blé et du mildiou de la pomme de terre.

Sur blés

PYGMALION® doit être appliqué dans le cadre d'un programme fongicide :

- Au stade 1-2 nœuds : PYGMALION® peut être appliqué en association avec un partenaire anti-septoriose ou seul uniquement sur variétés tolérantes (note > 6,5). La dose minimum d'utilisation est de 2 L/ha.

- Autour du stade Dernière feuille étalée : PYGMALION® est recommandé en association avec un partenaire anti-septoriose. La dose minimum d'utilisation est de 2L/ha.

Sur pomme de terre

PYGMALION® doit être appliqué dans le cadre d'un programme fongicide. Pour une performance optimisée, PYGMALION® ne doit pas être utilisé seul mais appliqué à 2 L/ha en association avec un partenaire anti-mildiou. Le partenaire sera choisi en fonction du stade de l'application et de la pression mildiou. Selon le partenaire choisi, sa dose d'application sera adaptée et pourra être réduite dans certains cas, pour optimiser le programme et réduire les IFT fongicides. Demandez conseil à votre technicien pour intégrer PYGMALION® dans votre itinéraire technique.

Sur cultures maraichères :

Dans le cadre des bonnes pratiques agricoles, selon la culture et la pression du parasite, PYGMALION® :

- Peut être utilisé seul en programme ou en association avec un fongicide si nécessaire et selon la pression parasitaire
- Doit être positionné en préventif
- Renouveler l'application en tenant compte de la croissance végétative et du délai minimum réglementaire entre deux applications.

• Précautions d'emploi

Il est recommandé d'adapter le volume d'eau au stade de développement de la culture et de soigner l'application afin que le produit recouvre bien l'ensemble de la végétation.

PYGMALION® est à l'abri du lessivage 2 heures après application. Si une pluie lessivante survient dans cet intervalle, renouveler la protection.

PYGMALION® est sélectif de la pomme de terre appliqué 3 fois et du blé appliqué 2 fois.

Nos préconisations sont issues d'essais réalisés sur plusieurs années. Cependant, plusieurs facteurs tels que les conditions climatologiques, techniques de traitement, mélanges non préconisés peuvent présenter des conséquences sur l'efficacité ou la sélectivité du traitement.

• Mélanges extemporanés

Les mélanges doivent être mis en œuvre conformément à la législation en vigueur et aux recommandations des guides de Bonnes Pratiques agricoles.

De nombreux mélanges fongicides ont été validés, demander conseil à votre interlocuteur DE SANGOSSE pour toute question. Pour tout mélange avec un engrais foliaire, nous consulter.

• Préparation de la bouillie

Après avoir rempli à moitié d'eau la cuve du pulvérisateur, verser PYGMALION® après les spécialités associées, puis terminer le remplissage en maintenant une agitation suffisante de la bouillie. Utiliser cette bouillie dans la journée.

• Pulvérisation

Prendre conseil auprès de notre service technique si nécessaire. Éviter d'atteindre le point de ruissellement, ajuster pression et vitesse d'avancement afin d'obtenir une couverture (en gouttelettes) suffisante de la végétation.

PREVENTION ET GESTION DE LA RESISTANCE

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance. De ce fait, DE SANGOSSE décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

MISE EN ŒUVRE REGLEMENTAIRE ET BONNES PRATIQUES






DSPF016 / PYGMALION
Part A - National Assessment
FRANCE

- **Stockage du produit**

Stocker le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

- **Protection de l'opérateur et du travailleur**

Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée. Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

		PROTECTION DE L'OPÉRATEUR PENDANT LES PHASES DE :										PROTECTION DU TRAVAILLEUR
		PRÉPARATION / RELANCE / CHARGEMENT	APPLICATION AVEC :								NETTOYAGE	
Caractéristiques des EPI			PULVÉRISATEUR PORTE-OU TRÔNE À RAMPE PNEUMATIQUE OU ATÔMEUR PULVÉRISATION VERS LE BAS TRACTEUR AVEC CABINE FERMÉE	TRACTEUR SANS CABINE	PULVÉRISATEUR PORTE-OU TRÔNE À RAMPE PNEUMATIQUE OU ATÔMEUR PULVÉRISATION VERS LE HAUT TRACTEUR AVEC CABINE FERMÉE	TRACTEUR SANS CABINE	LANCE / CULTURES BASSES (< 50 cm)	LANCE / CULTURES HAUTES (> 50 cm)	PULVÉRISATEUR À LA BOS	LANCE SOUS ARBRES		
GANTS EN NITRILE NF EN ISO 374-1/A1 (réutilisables NF EN 15523-1+A1 (type A) ou à usage unique NF EN ISO 374-2 (types A, B ou C))		Réutilisables	À usage unique*	À usage unique*	À usage unique*	À usage unique*	Réutilisables	Réutilisables	Réutilisables	Réutilisables	Réutilisables	Réutilisables**
EPI VESTIMENTAIRE conforme à la norme NF EN ISO 27065:01		EPI vestimentaire ET EPI partiel										EPI vestimentaire ET EPI partiel
EPI PARTIEL Blouse ou t-shirt à manches longues catégorie II (type PBD)		EPI partiel										EPI partiel
COMBINAISON DE PROTECTION CHIMIQUE catégorie III type 3 ou 4		Type 4				Type 4 avec capuche		Type 4 avec capuche	Type 4 avec capuche	Type 4		Type 4
BOTTES certifiées EN 13 832-3:2005												

* EN CAS D'INTERVENTION SUR LE MATÉRIEL PENDANT LA PHASE DE PULVÉRISATION, DANS CE CAS, LES GANTS NE DOIVENT ÊTRE PORTÉS QU'À L'EXTÉRIEUR DE LA CABINE ET DOIVENT ÊTRE STOCKÉS APRÈS UTILISATION À L'EXTÉRIEUR DE LA CABINE.
** EN CAS DE CONTACT AVEC LA CULTURE TRAITÉE.

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.

- **Nettoyage du pulvérisateur et gestion des fonds de cuve**

A la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses...) doit être rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

- **Élimination du produit, de l'emballage**

Réemploi de l'emballage interdit.

Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.

Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

- **En cas de déversement accidentel**

Se protéger (EPI) et sécuriser la zone.

Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens.

Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse.

Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.



AVERTISSEMENT Toute reproduction totale ou partielle de cette étiquette est interdite.

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les Autorités Compétentes françaises. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.